Covidien LLC
% Ms. Kristi Fox
Principal Regulatory Affairs Specialist
161 Cheshire Lane N, Suite 100
PLYMOUTH MN 55441

August 7, 2019

Re: K191394
Trade/Device Name: ILLUMISITE™ Platform
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: Class II
Product Code: JAK
Dated: May 23, 2019
Received: May 24, 2019

Dear Ms. Fox:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see

https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K191394

Device Name
ILLUMISITE™ Platform

Indications for Use *(Describe)*

Indicated for displaying images of the tracheobronchial tree to aid the physician in guiding endoscopic tools or catheters in the pulmonary tract and to enable marker placement within soft lung tissue. It does not make a diagnosis and is not an endoscopic tool. Not for pediatric use.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

ILLUMISITE™ Platform

The contents of the 510(k) Summary have been provided in conformance with 21 CFR 807.92.

1. Submitter

510(k) Submitter:

Covidien llc
161 Cheshire Lane, Suite 100
Plymouth, MN 55441 USA

Contact Person:

Kristi Fox
Principal Regulatory Affairs Specialist
Phone: 763-647-5553
Fax: 763-210-4098
Email: kristin.fox@medtronic.com

Date Prepared: May 23, 2019

2. Subject Device

Trade Name :	ILLUMISITE Platform
Common Name:	Electromagnetic Navigation Bronchoscopy System
Classification Name:	Computed tomography x-ray system 21 CFR 829.1750
Product code:	JAK
Regulatory Class:	II
Manufacturer:	Covidien llc

3. Predicate Device

Device Name :	superDimension™ Navigation System
Common Name:	Electromagnetic Navigation Bronchoscopy System
510(k):	K173244
Classification Name:	Computed tomography x-ray system 21 CFR 829.1750
Product code:	JAK
Regulatory Class:	II
Manufacturer:	Covidien llc

4. Device Description

The ILLUMISITE™ Platform is an image-guided electromagnetic navigation system used to guide catheters or endoscopic tools to predetermined targets in or adjacent to the bronchial tree on a path identified by CT scan. During a procedure, the physician navigates endoscopic tools to targets in the lungs such as lymph nodes and solitary pulmonary nodules.

The ILLUMISITE™ Platform, is a modification to the previously cleared predicate device, the superDimension™ navigation system. The primary difference is the ability of the ILLUMISITE Platform to provide continuous positional feedback throughout the procedure (i.e. continuous guidance) via a sensor in the extended working channel. The system console hardware, software, and extended working channel have been modified to incorporate the continuous guidance navigation feature.

5. Indications for Use

Indicated for displaying images of the tracheobronchial tree to aid the physician in guiding endoscopic tools or catheters in the pulmonary tract and to enable marker placement within soft lung tissue. It does not make a diagnosis and is not an endoscopic tool. Not for pediatric use.

6. Summary of Characteristics Compared to Predicate Device

The subject and predicate devices have the same indications for use, principle of operation, fundamental technology, and inherent design. The primary difference between the proposed ILLUMISITE™ Platform and the predicate is to expand upon the existing sensing capability by enabling continuous guidance through the integration of a sensor in the extended working channel and updates to the system console hardware and software. Other changes have been made to update hardware components to current technology and to integrate a fiducial marker board, used for the existing optional local registration feature, into the location board.

Design verification and validation test results demonstrate that the changes do not affect the safety and effectiveness of the device as the subject device conforms to the requirements and specifications of the device. The table below summarizes the differences between the predicate device and the proposed device.

Characteristic	superDimension™ Navigation System (Predicate Device – K173244)	ILLUMISITE™ Platform (Proposed Device)
Intended Use Comparison		
Indications for Use	Indicated for displaying images of the tracheobronchial tree to aid the physician in guiding endoscopic tools or catheters in the pulmonary tract and to enable marker placement within soft lung tissue. It does not make a diagnosis and is not an endoscopic tool. Not for pediatric use.	Same
Anatomical Site	Lung, airways and tracheobronchial tree	Same
Technology Comparison		
Basic principle	Guide endoscopic tools, catheters, and markers to a target on path indicated by CT scan and provide visualization of pulmonary tract and target.	Same, except guidance and visualization is additionally provided after locatable guide removal via a sensor in the distal tip of the extended working channel.
Visualization Principle	Position predicted based on measured position and orientation of tip and localizing device as determined by electromagnetic sensors.	Same, with an additional sensor added to the extended working channel

Characteristic	superDimension™ Navigation System (Predicate Device – K173244)	ILLUMISITE™ Platform (Proposed Device)
Method for tracking location of instrument	Electromagnetic sensors on tip of locatable guide	Electromagnetic sensors on the tip of the locatable guide **and** on the tip of the extended working channel
Registration Modes	Automatic and manual process of matching of registration points selected during Planning to the patient's anatomy (CT-to-Body Registration) Optional local registration feature updates the catheter position in the ENB system based on the 3D position of the catheter relative to the target during the local registration process.	Same, automatic registration algorithm has been modified to enhance the registration.
Navigation	Navigates to targets to perform biopsy or other procedure using single use components, console system and software.	Same
Accuracy Check	System accuracy test completed as part of installation and maintenance Fluoroscopic accuracy tested completed as part of installation	Same with the addition of a system accuracy test for the extended working channel sensor
System Accuracy	≤3mm root mean square (RMS) based on accuracy bench testing	Same
Software Comparison		
Procedure Application	Version 7.2	ILLUMISITE Version 1.0 Fundamental technology and primary workflow remains the same.
Planning Application	Version 7.1	ILLUMISITE Version 1.0 Fundamental technology and primary workflow remains the same.
Hardware Comparison		
Hardware	• Console: IPC, LSS, UPS, monitor, keyboard, mouse • Planning laptop computer • Cables (LG, PST) • Location board • Fiducial marker board • Video cable	• Console: IPC, CGS, UPS, monitor, keyboard, trackball • Cables (LG, EWC (sensor), PST) • Location board with integrated fiducial markers • Video cables
Use of computer and computer type	Industrial PC Laptop provided by Covidien as part of the system	Equivalent Industrial PC Predicate Laptop compatible (laptop sold separately)
Location Board	• Board that generates signals used for localization by the LSS • Fiducial marker overlay	• Board that generates signals used for localization by the CGS • Integrated fiducial markers within the location board
Localization Electronics	Location Subsystem (LSS)	Continuous Guidance System (CGS)
Patient Sensor	Sensors placed on the patient	Same
User Input Devices (Peripherals)	Monitor Keyboard	Monitor Keyboard

Characteristic	superDimension™ Navigation System (Predicate Device – K173244)	ILLUMISITE™ Platform (Proposed Device)
	Mouse Infrared remote control Footswitch	Trackball Dual footswitch
Single Use Disposable Accessories Comparison		
Extended Working Channel		
Minimum Inner Diameter (ID)	2.0 mm	Same
Outer Diameter (OD)	2.7 mm	Same
Working Length	1070 mm	Same
Sensors	Not applicable	Continuous wind coil sensor
Tip Shape Offering	45°, 90°, 180°, 190°, Medial, Straight	45°, 90° and 180°
Sterility	Sterilized by EtO SAL 10^{-6}	Same
Telescope – No change between predicate and proposed device		
Measuring Tube – No change between predicate and proposed device		
Locatable Guide – No change between predicate and proposed device		
Bronchoscope Adapter – No change between predicate and proposed device		
Single Use Non-Sterile Disposable Accessories Comparison		
Patient Sensor Patch – No change between predicate and proposed device		

7. Performance Data

The ILLUMISITE Platform was subjected to the Covidien design control process. Risk Management was performed to analyze the potential hazards associated with the changes. Appropriate design verification and validations were performed to assure the ILLUMISITE Platform continues to meet its intended use.

Design testing performed on the ILLUMISITE Platform included the following:

- Software and firmware verification testing
- Electrical safety and electromagnetic compatibility of the ILLUMISITE console hardware, locatable guide, and extended working channel
- Biocompatibility, sterilization, and shelf life testing of the extended working channel
- Design verification including mechanical, packaging, and hardware component testing
- Design validation testing with qualified physicians, clinicians, and service personnel to confirm functionality and user interface

The combined verification and validation testing confirmed that the ILLUMISITE Platform met its product specification and system requirements.

Design validation was successfully performed under simulated use conditions by representative users including physicians, clinicians, and service personnel. Each user group performed typical use scenarios defined in the design validation protocol. In conclusion, the design validation study ensured that the ILLUMISITE Platform conformed to defined user needs and intended uses.

The ILLUMISITE is in compliance with the applicable parts of the following International and FDA-recognized consensus standards:

- ISO 14971: 2007 Medical Devices - Application of Risk Management to Medical Devices
- IEC 62366-1: 2015 Medical devices - Part 1: application of usability engineering to medical devices
- ANSI/AAMI/IEC 62304: 2006 + A1: 2015 Medical device software - software life cycle processes
- IEC 60601-1: 2005 + A1: 2012 Medical electrical equipment - part 1: general requirements for basic safety and essential performance
- IEC 60601-1-2: 2014 Medical electrical equipment - part 1-2: general requirements for basic safety and essential performance - collateral standard: electromagnetic disturbances - requirements and tests
- IEC 60601-1-6: 2013 Medical electrical equipment- part 1-6: general requirements for basic safety and essential performance - collateral standard: usability
- IEC 60601-2-18:2009 - Medical electrical equipment - Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment
- ISO 11135: 2014 Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices
- ISO 11737-1:2006 (Corr l :2007) Sterilization of Medical Devices- Microbiological methods -Part 1: Determination of a population of microorganisms on products
- ISO 11737-2:2009 Sterilization of Medical Devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation, and maintenance of a sterilization process
- ISO 14644-1:2015 Cleanrooms and associated controlled environments - Part 1: Classification of air cleanliness - Parts applicable to a Class 7 clean room only
- ISO 11607-1: 2006 + A1: 2014 Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems
- ISO 11607-2:2006+Al:2014 Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes
- ASTM D4169:2016 Standard Practice for Performance Testing of Shipping Containers and Systems
- ASTM F88:2015 Standard Test Method for Seal Strength of Flexible Barrier Materials
- ASTM F2096:2011 Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble Test)
- ASTM F1980:2016 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
- ISO 15223-1: 2016 Medical devices - symbols to be used with medical device labels, labelling, and information to be supplied - part 1: general requirements.
- ISO 10993-1: 2009 (Corr 1:2010) Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process
- ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: tests for in vitro cytotoxicity
- ISO 10993-7:2008 Biological evaluation of medical devices - Part 7: ethylene oxide sterilization residuals
- ISO 10993-10:2010 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization

- ISO 10993-11:2006 Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
- ISO 10993-12:2012 Biological evaluation of medical devices - Part 12: Sample Preparation and Reference Materials

8. Clinical Data

Clinical tests were not required to validate the changes to the ILLUMISITE Platform and accessories.

9. Conclusion

The ILLUMISITE Platform has the same indications for use, principle of operation, fundamental scientific technology, and performance characteristics as the predicate device as demonstrated through performance data. Any new risks identified in comparison to the predicate device have been assessed in the device risk assessment per the ISO 14971 Risk Management standard. The modifications within the ILLUMISITE Platform and its accessories that allow continuous navigation guidance, do not significantly change the overall device risks. Therefore, Covidien llc considers the ILLUMISITE Platform to be substantially equivalent to the legally marketed predicate device; superDimension navigation system, cleared under 510(k) K173244.